K030071

APR 2 6 2004

510 (k) Summary
as required by section 807.92(c)

Subscribers Name & Address

Maquet Critical Care AB
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Contact Person and Official correspondent: Veronica Ekstroem, Regulatory Affairs

Official Correspondent: Jamie Yieh, Regulatory Affairs Manager
Maquet Inc., 1140 Route 22 East, Suite 202, Bridgewater, NJ 08807

Trade Name

Servo Guard Part No 64 81 290 EH88H

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Breathing Circuit Bacteria Filter		II	21 CFR 868.5260

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Siemens Main Flow Bacteria Filter	K871366
End expiratory filter, Model RT020	K002839

Device Description (for detailed description see Section F)

The Servo Guard is an efficient bacterial and viral filter for applications in respiratory care and anesthesia. The Servo Guard is a disposable single-use device that provides filtration for reducing possible cross contamination between patient and equipment.

Intended Use of the Device:

The Servo Guard is an efficient bacterial and viral filter for applications in respiratory care and anesthesia. The Servo Guard is a disposable single-use device that provides filtration for reducing possible cross contamination between patient and equipment.

Summary of technological characteristics of Device and Predicate Device:

The dimensions of the three devices are different. The Servo Guard filter has a more efficient bacterial/viral filtration than the predicate devices. The Servo guard may be used both on the inspiratory and the expiratory limbs of the breathing circuit, while the RT020 only can be used on the expiratory side.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2004

Mr. Jamie Yieh
Maquet Medical, Inc.
1140 Route 22E Suite 202
Bridgewater, New Jersey 08807

Re: K030071
Trade Name: Servo Guard Model 64 81 290 EH88E
Regulation Number: 868.5260
Regulation Name: Bacterial Breathing Circuit Filter
Regulatory Class: II
Product Code: CAH
Dated: March 3, 2004
Received: March 8, 2004

Dear Mr. Yieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Servo Guard

Indications For Use:

The Servo Guard is a disposable single-use device that provides filtration for reducing possible cross contamination between patient and equipment. The device is intended for adult, pediatric and infant populations. The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030071